DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

M2300.1

cc: HFI-35/FOI Staff
DWA

January 11, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 13

Curt Noyes
Executive Vice President
Dakota Clinic, Ltd.
1702 S. University Drive, P.O. Box 6001
Fargo, North Dakota 58108-6001

Dear Mr. Noyes,

Your mobile mammography operation (MQSA certificate #214486) was inspected on December 4, 1998. A representative of the State of North Dakota, acting on behalf of the Food and Drug Administration (FDA), conducted the inspection. This inspection revealed a serious regulatory problem involving mammography at your facility.

Under a United States federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirement for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings at your facility:

1. Based on the documentation your site supplied during the inspection it appears that interpreting physician [redacted] is not licensed by a State to practice medicine.

2. Based on the documentation your site supplied during the inspection it appears that interpreting physician ~~~~~ does not meet the requirement of (a) being board certified by any of the approved boards, or (b) having had two months of full-time training in interpretation of mammograms (equivalent to 280 hours). This may include time spent in residency, if documented by the residency program. A self-attestation is **not** acceptable.

The specific problems noted above appeared on your MQSA Facility Inspection Report which were issued to your facility following the close of the inspection. These problems are identified as Level 1 because they identify a failure to meet a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure or each day of failure to substantially comply with MQSA standards, suspension or revocation of your facility's FDA certificates, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to your site at the conclusion of the inspection. The Level 2 findings are:

3. Based on the documentation your site supplied during the inspection it appears that interpreting physician ~~~~~ does not meet the **initial** training requirement of having 40 hours of CME (continuing medical education) in mammography. Note: If the physician meets paragraph 2 via route (b) then they are exempt from this paragraph.

4. Based on the documentation your site supplied during the inspection it appears that interpreting physician ~~~~~ does not meet the

initial experience requirement of having read and interpreted mammograms from the examinations of at least 240 patients in a six-month period.

5. Based on the documentation your site supplied during the inspection it appears that interpreting physician [redacted] does not meet the **continuing** experience requirement of having read and interpreted mammograms from an average of 40 patient examinations per month over 24 months.

6. Interpreting physician [redacted] did not meet the **continuing** education requirements of having completed a minimum of 15 credits in mammography over a 3-year period.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within 15 working days from the date you received this letter:

* the specific steps you have taken to correct all of the violations noted in this letter;

* each step your facility is taking to prevent the recurrence of similar violations;

* equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

* sample records that demonstrate proper record keeping procedures, if the non-compliances that were found relate to quality control or other records (Note: Patient names or identification should be deleted from any submitted copies).

Please submit your response to:

Tom Garvin
Radiological Health Specialist
Food and Drug Administration
2675 N. Mayfair Road, Suite 200
Milwaukee, WI 53226-1305.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting:

Mammography Quality Assurance Program
Food and Drug Administration
P.O. Box 6057
Columbia, MD 21045-6057
(1-800-838-7715) or *http://www.fda.gov*

If you have more specific questions about mammography facility requirements, or about the content of this letter please feel free to contact Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,

James A. Rahto
Director
Minneapolis District

TWG/ccl

xc: Dana Mount
Director, Division of Environmental Engineering
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